JUL 19 2013

510(k) Summary

Device Trade Name: Stabiliz Fixation System with SPL Locking Screw

Manufacturer:
Stabiliz Orthopaedics, LLC
665 Stockton Drive
Exton, PA 19341

Contact:
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Prepared by:
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Date Prepared: July 18, 2013

Classifications:
21 CFR 888.3040: Smooth or threaded metallic bone fixation fasteners

and

21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Codes: HWC and HRS

Indications for Use:
The Stabiliz Fixation System with SPL Locking Screw is intended for fixation of fractures, osteotomies and nonunions of the humerus, radius, ulna, distal tibia, and fibula.

Device Description:
The Stabiliz Fixation System includes standard straight LCP plates, metal locking screws, cortical screws, fully-threaded cancellous screws, and partially-threaded cancellous screws in various sizes and geometries. The SPL Locking Screw is a metal locking screw with a resorbable threaded polymer collar.

Predicate Devices:
Data provided in the 510(k) support the substantial equivalence of the Stabiliz Fixation System to the following predicate devices: Stabiliz Fixation System (K120651); Zimmer® MotionLoc Screws (K123918 and K101696); Synthes 3.5mm Broad LC-DCP Plate (K020872); and Biomet Orthopedics Lactosorb® Tibial L-15 Screw and Washer (K033233).

Substantial Equivalence:
The components of the Stabiliz Fixation System are substantially equivalent to the identified predicates with respect to indications for use, geometry, available sizes, materials, methods of fixation to bone, and performance.

Preclinical Testing:
The non-clinical tests performed by the company include *in vitro* degradation testing, biomechanical loading study, corrosion testing, and biocompatibility testing. The results demonstrate that the Stabiliz Fixation System is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 19, 2013

Stabiliz Orthopaedics, LLC
% Douglas L. Cerynik,M.D.
President & CEO
665 Stockton Drive
Exton, Pennsylvania 19341

Re: K130731
Trade/Device Name: Stabiliz Fixation System with SPL Locking Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 18, 2013
Received: June 19, 2013

Dear Dr. Cerynik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130731

Device Name: Stabiliz Fixation System with SPL Locking Screws

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Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lori A. Wiggins

Division of Orthopedic Devices